

**1. Date of preparation**

SEP 15 2005

September 01, 2005

**2. Company information**

BarcoView  
35 President Kennedypark  
B-8500 Kortrijk, Belgium  
Tel. +32-(0)56-233-211  
Fax +32-(0)56-233-457

**3. Contact person**

Lieven De Wandel  
Official correspondent

**4. Device information**

- Trade name: Coronis 3MP-21"
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

**5. Predicate device**

- Name: Coronis 3MP Medical flat panel display system
- 510(k) number: K013922
- Manufacturer: Barco NV

**6. Device description**

Coronis 3MP-21" is a display system for medical viewing. It consists of 3 components:  
MFGD 3621 is a 21.3" grayscale LCD display. BarcoMed Coronis is a fast high-resolution display controller board that plugs into a PACS workstation computer. MediCal Pro is user-friendly softcopy QA software.

The display system can be a single-head system or multi-head system. In the last case it contains multiple displays and display controller boards.

**7. Intended use**

"The Coronis 3MP-21" is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

## **8. Summary of technological characteristics**

The device consists of three components:

- One 3-megapixel flat panel display (MFGD 3621)
- One 10-bit display controller board (BarcoMed Coronis)
- MediCal Pro software

The flat panel display has a resolution of 2048 x 1536 pixels. It can be used in landscape and portrait mode.

The display controller board is an ultra-high speed board with a 10-bit in, 10-bit out look-up table, providing 1024 simultaneous levels of gray.

The MediCal Pro software provides fully automated image quality assurance. It maintains and logs display viewing performance, automates QA tasks and sets up system calibration.

Compared to the predicate device, the display of the Coronis 3MP-21" system has a different LCD panel with somewhat larger screen size. The other components of the system are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco Coronis 3MP-21" is substantially equivalent to the predicate device, Coronis 3MP Medical flat panel display system.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco Coronis 3MP-21" contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

**510(k) Summary**  
In accordance with 21 CFR 807.92

**1. Date of preparation**

September 01, 2005

**2. Company information**

BarcoView  
35 President Kennedypark  
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Tel. +32-(0)56-233-211  
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**3. Contact person**

Lieven De Wandel  
Official correspondent

**4. Device information**

- Trade name: MFGD 3621
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

**5. Predicate device**

- Name: MFGD 2320 20-inch 2 Megapixel grayscale display
- 510(k) number: K033004
- Manufacturer: Barco NV

**6. Device description**

MFGD 3621 is a 21.3" grayscale LCD display for medical viewing. It is combined with MediCal Pro, a user-friendly softcopy QA software.

**7. Intended use**

The MFGD 3621 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

**8. Summary of technological characteristics**

The flat panel display has a resolution of 2048 x 1536 pixels. It can be used in landscape or

portrait mode.

The MediCal Pro software provides fully automated image quality assurance. It maintains and logs display viewing performance, automates QA tasks and sets up system calibration.

Compared to the predicate device, the MFGD 3621 display has a different LCD panel with larger screen size and higher resolution.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco MFGD 3621 is substantially equivalent to the predicate device, MFGD 2320 20-inch 2 Megapixel grayscale display.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MFGD 3621 contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.



SEP 15 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Lieven De Wandel  
Official Correspondent  
BarcoView – Medical Imaging Systems  
President Kennedypark 35  
B-8500 Kortrijk  
BELGIUM

Re: K052429  
Trade/Device Name: Coronis 3MP-21”  
and MFGD 3621  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: September 1, 2005  
Received: September 8, 2005

Dear Mr. De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

2 Enclosures

## INDICATIONS FOR USE

510(k) Number (if known): K052429

Device Name: Coronis 3MP-21"

### Indications for Use:

"The Coronis 3MP-21" is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use XX

(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K052429

## INDICATIONS FOR USE

10(k) Number (if known): K052429

Device Name: MFGD 3621

### Indications for Use:

"The MFGD 3621 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use XX

(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brody  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K05-2429